



## **Microbac Protocol**

### **VIRUCIDAL HARD-SURFACE EFFICACY TEST -**

### **Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-CoV-2) (COVID-19 Virus)**

#### **Testing Facility**

**Microbac Laboratories, Inc.  
105 Carpenter Drive  
Sterling, VA20164**

#### **Prepared for**

**W.M. Barr & Company, Inc.  
6750 Lenox Center Court  
Suite 200  
Memphis, TN 38115**

**April 30, 2020**

Microbac Protocol: 640.2.04.13.20

Microbac Project: 640-105

Microbac Laboratories, Inc.  
105 Carpenter Drive | Sterling, VA 20164 | 703.925.0100 p | 703.925.9366 f | [www.microbac.com](http://www.microbac.com)

## OBJECTIVE:

This test is designed to substantiate virucidal effectiveness claims for a liquid or spray test substance to be labeled as a virucide. It determines the potential of the test substance to disinfect hard surfaces contaminated with the test virus. The test is designed to simulate consumer use and conforms to EPA OCSP 810.2000 (2018) and 810.2200 (2018) Product Performance Test Guidelines, Frequently Asked Questions (FAQ) for OCSP 810.2000 (2018), 810.2100 (2018), and 810.2200 (2018), as well as the Health Canada “Guidance Document – Safety and Efficacy Requirements for Hard Surface Disinfectant Drugs” (January 2014). This protocol follows the procedure outlined in the ASTM International test method designated E1053-20, “Standard Test Method to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces”. The study design also aligns with EPA guidance provided to Scientific & Regulatory Consultants, Inc. (Letter from K. Willis, EPA OPP AD Science Branch Chief, March 25, 2020).

## TESTING CONDITIONS:

Virus will be dried on a suitable sterile hard surface at ambient temperature. Three lots of one test substance (liquid) will be tested in compliance with the EPA Lower Certified Limit Policy in 810.2000 at one contact time and one replicate (N=1). The test substance will be used to treat the dried virus on a glass Petri dish carrier. One carrier will be tested for each lot of test substance and the appropriate controls. After a defined exposure period as specified by the Sponsor, the test substance-virus mixture will be neutralized, scraped off from the surface, collected, and tested for the presence of infectious virions.

## MATERIALS:

- A. Test, control and reference substances will be supplied by the Sponsor of the study. Microbac will append the Sponsor-provided Certificate(s) of Analysis (CoA) to this study report, as per CFR 40.160.105:
- The identity, strength, purity, and composition, or other characteristics which will appropriately define the test, control, or reference substance shall be determined and shall be documented by the Sponsor before its use in a study. Methods of synthesis, fabrication, or derivation of the test, control, or reference substance shall be documented and retained by the Sponsor.

When relevant to the conduct of the study the solubility of each test, control, or reference substance shall be determined by the Sponsor before the experimental start date. The stability of the test, control, or reference substance shall be determined by the Sponsor before the experimental start date or concomitantly according to written standard operating procedures, which provide for periodic analysis.

The test substance will be tested as supplied by the Sponsor unless directed otherwise. All operations performed on the test substance such as dilution or specialized storage conditions must be specified by the Sponsor before initiation of testing.

The Sponsor assures Microbac testing facility management that the test substance/formulation has been appropriately tested for identity, strength, purity, stability, and uniformity as applicable.

Microbac will retain all unused test substances for a period of one year upon completion of the test, and then discard them in a manner that meets the approval of the safety officer or return them to the Sponsor. The test materials and the paper records will be retained in accordance with FIFRA. Microbac will contact the Study Sponsor to arrange for transfer of records when/if the test substance is returned to the Sponsor.

B. Materials supplied by Microbac, including, but not limited to:

1. Challenge virus (requested by the Sponsor of the study): Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-CoV-2) (COVID-19 Virus) (SARS-Related Coronavirus 2), Strain: USA-WA1/2020, Source: BEI Resources, NR-52281. Strain USA-WA1/2020 was isolated from an oropharyngeal swab from a patient with a respiratory illness who had recently returned from travel to the affected region of China and developed clinical disease (COVID-19) in January 2020 in Washington, USA (<https://www.beiresources.org/Catalog/animalviruses/NR-52281.aspx>).
2. Host cell line: Vero E6 cells, ATCC CRL-1586
3. Laboratory equipment and supplies.

4. Fetal Bovine Serum or another appropriate source of serum as the soil load used for testing with SARS-CoV-2 (if applicable) as requested by the Sponsor.
5. Media and reagents:

Media and reagents relevant to the virus-host system and test substance being tested will be documented in the first project sheet and data pack.

#### **TEST SYSTEM IDENTIFICATION:**

All Petri dishes, dilution tube racks, and host-containing apparatus will be appropriately labeled with the following information: virus, host, and test substance and/or project number.

#### **EXPERIMENTAL DESIGN:**

All of the procedures involved in performance of this study are described in a detailed series of SOPs that are maintained at Microbac. SOPs and Logs are referred to in the raw data and are required as part of GLP regulations. The study flow diagram is shown in Figure 1, with details described in the following sections.

FIGURE 1



DM: Dilution Medium

NE/VI: Neutralizer Effectiveness/Viral Interference control CT: Cytotoxicity Control

Note: One test substance, three lots, will be tested at one exposure (contact) time and one replicate (N=1). The NE/VI and CT controls will be performed at one replicate per lot.

#### A. Inoculum preparation:

Viral stocks are purchased from reputable sources that identify them by scientifically accepted methods and may have been further propagated at Microbac. Records are maintained that demonstrate the origin of the virus. The virus stocks are stored at an ultra-low temperature.

Frozen viral stocks will be thawed on the day of the test. Serum will be added to the viral stock to achieve an organic load of 5.0% (if not already 5.0%), unless otherwise directed by the Sponsor and pre-agreed by Microbac. If the challenge virus culture is

standardized by concentration or dilution, or if a column is used, these manipulations must be documented and reported.

Note: A level of approximately 4.8 – 6.3 Log<sub>10</sub> virus challenge per carrier (as indicated by the plate recovery control load) when there is no cytotoxicity associated with the test substance, or approximately 3.0 – 4.5 Log<sub>10</sub> per carrier beyond the level of cytotoxicity when present, should be achieved whenever possible.

B. Carrier preparation:

For each lot of the test substance an aliquot of 0.4 mL of stock virus will be added, and spread with a cell scraper over the bottom of pre-sterilized glass Petri dishes (100mm diameter). This volume will remain consistent among all test and control runs. Carriers treated with virus will be dried at ambient temperature. The drying time, temperature, and relative humidity will be recorded and reported.

One carrier will be prepared for each lot of the test substance using virus. One carrier will be prepared for the plate recovery control using virus. Additionally, one carrier will be prepared for each lot of test substance for the neutralizer effectiveness/viral interference and cytotoxicity controls using dilution media in lieu of virus as the inoculum.

C. Test substance preparation:

Note: Information on the identity, strength, purity, stability, uniformity, and dose solution analysis of the test substance/formulation resides with the Sponsor of the study.

The test substance will be prepared exactly according to the Sponsor's directions (if provided). If the Sponsor requests dilution of the test substance, the diluted test substance will be used for testing within three hours of preparation. The prepared test substance, if not within the stipulated test temperature range, will be pre-equilibrated to the test temperature prior to use in the study as applicable.

D. Test:

Three lots of the test substance (liquid) will be tested at one contact time and one replicate (N=1). Note: The temperature and relative humidity during the exposure period will be recorded and reported.

For direct liquid application test substance, for each run, after the inoculum has dried, 2.0 mL of the test substance will be added. After addition, a stopwatch will immediately be started to measure the contact time. The dried virus film must be completely covered by the test substance. The plates will remain at the temperature and for the time specified by the Sponsor. After the contact period, the test substance will be neutralized with 2.0 mL of appropriate neutralizer and the mixture will be scraped from the surface of the dish with a cell scraper. This post-neutralized sample (PNS) will be considered approximately a  $10^{-1}$  dilution. The temperature and relative humidity during the exposure period will be recorded and reported.

For a spray application test substance, an aliquot of the test substance, ready-to-use, will be dispensed into a sterilized spray bottle, if not provided by the Sponsor. Unless otherwise directed by the Sponsor, the spray bottle will then be shaken 2 – 3 times to ensure homogeneity and sprayed to charge the spray bottle. A mock spray action will be performed by applying the test substance as the Sponsor directs onto at least two blank Petri dishes. Then the volume dispensed onto each dish will be measured and averaged. This averaged volume from the mock spray runs will be used for the neutralizer volume for all applicable runs and for the Plate recovery control runs. The test substance will be sprayed onto the virus carriers in a horizontal position until thoroughly wet from a distance of 6" – 8" or as directed by the Sponsor. Each carrier will be held in a horizontal position for the exposure time as specified by the Sponsor. After the contact period, the test substance will be neutralized with an appropriate neutralizer using the averaged volume from the mock spray runs. The neutralizer-test substance mixture will be scraped off from the surface of the dish with a cell scraper. This post-neutralized sample (PNS) will be considered approximately a  $10^{-1}$  dilution. The temperature and relative humidity during the exposure period will be recorded and reported.

If Sephacryl columns are used to aid in the neutralization and to further reduce the cytotoxicity, each inoculum/test substance/neutralizer mixture sample will be loaded onto a pre-spun Sephacryl column. Following the passage through columns, the eluates will be aseptically collected and serially ten-fold diluted in DM. If columns are not used, serial ten-fold dilutions of the inoculum/test substance/neutralizer mixture will directly be prepared in DM.

E. Infectivity assay:

The residual infectious virus in all test and control samples will be detected by viral-induced cytopathic effect (CPE).

Selected dilutions of the neutralized inoculum/test substance mixture (test samples) and control samples will be added to cultured host cells (at least four wells per dilution, per reaction mixture) and incubated at  $36\pm 2^{\circ}\text{C}$  with  $5\pm 3\%$   $\text{CO}_2$  for total 4 – 9 days. The host cells may be washed twice with phosphate buffered saline prior to inoculation. The inoculated culture will be observed and refed with fresh media as necessary, during the incubation period. These activities, if applicable, will be recorded. The host cells will then be examined microscopically for presence of infectious virions. The resulting virus-specific CPE and test substance-specific cytotoxic effects will be scored by examining all test and control samples. These observations will be recorded.

F. Controls:

1. Plate recovery control (PRC):

This concurrent control will be performed with a single inoculated carrier, concurrently with the test substance runs. The temperature and relative humidity during the exposure period will be recorded and reported.

The virus inoculum will be spread over the surface of a sterile glass Petri dish and left to dry at ambient temperature. A volume of DM equivalent to that of the test substance will be added to the dried virus and the plate held for the Sponsor requested contact time at the requested exposure temperature. Post-contact time, virus will be subjected to the identical neutralization procedure as used for the test substance. Serial 10-fold dilutions of the samples will be prepared in DM and selected dilutions of the sample will be added to cultured cell monolayers at a minimum of four wells per dilution per sample, as described in Section E “Infectivity Assay”. This control will determine the relative loss in virus infectivity resulting from drying and neutralization alone.

To achieve a valid test, at least  $4.8\text{-Log}_{10}$  of infectious virus per carrier must be recovered from this control following drying and neutralization. The titer from this control will be used to calculate the  $\log_{10}$  reduction of the virus titer

post treatment with the test substance (see below).

2. Neutralizer effectiveness/Viral interference control (NE/VI):

This concurrent control will determine if residual active ingredient is present after neutralization and if the neutralized test substance interferes with the virus infection system. This control will be performed for each lot of test substance at one replicate per lot concurrently with testing. The temperature and relative humidity during the exposure period will be recorded and reported.

The test substance will be processed exactly as the test procedure but in lieu of virus inoculum, dried DM will be exposed to the test substance and assayed as previously described. Post-treatment and neutralization, the neutralized DM/test substance mixture will be divided into two portions, one for the cytotoxicity control and the other for the neutralizer effectiveness/viral interference control and processed as in the test.

If columns are used, each portion will be passed through individual columns and the eluate will be serially diluted ten-fold in DM. If columns are not used, each portion will be directly diluted using serial ten-fold dilutions in DM.

The neutralizer effectiveness/viral interference control sample will be diluted as follows: using dilution test tubes and appropriate pipette, an aliquot of the PNS will be used for making serial 10-fold dilutions in DM (for example, 0.5 mL sample + 4.5 mL DM). Following serial dilution, 0.1 mL of a low titered virus, containing approximately 1,000 – 5,000 infectious units of virus, will be added to 4.5 mL of each dilution and held for a period of no shorter than the contact time.

Selected dilutions of these samples will be added to cultured cell monolayers at a minimum of four wells per dilution per sample, as described in the “Infectivity Assay” section.

3. Cytotoxicity control (CT):

This concurrent control will be performed for each lot of test substance at one replicate per lot.

The cytotoxicity sample, acquired from the neutralizer effectiveness/viral interference control run, will be diluted and have no virus added. Selected dilutions will be inoculated onto host cells and incubated in the same manner as the rest of the test and control samples. Cytotoxicity will be scored at the same time as the test samples; cytotoxic effects are distinct from virus-induced cytopathic effects, which will be evident in the plate recovery control cultures.

4. Column titer control (to be performed only if a Sephacryl column is used):

This concurrent control will be performed to determine any affect the columns may have on infectious virus titer. It will be performed in a single run.

The sample for this control will be acquired from a portion of the PRC, prior to passing through the columns and will be serially diluted in DM, then processed in the same manner as the test.

5. Cell viability control:

This concurrent control will be performed in a single run. It will demonstrate that cells remain viable throughout the course of the assay period. In addition, it will confirm the sterility of the DM employed throughout the assay period. At least four wells of cells will receive only DM and will be incubated and processed with both test and other controls. This will serve as the negative control.

6. Virus Stock Titer control (VST)

This concurrent control will be performed in a single run. An aliquot of the virus used in the study will be directly serially diluted and inoculated onto the host cells to confirm the titer of the stock virus. This control will demonstrate that the titer of the stock virus is appropriate for use and that the viral infectivity assay is performed appropriately.

G. Calculation:

The 50% tissue culture infective dose per mL (TCID<sub>50</sub>/mL) will be determined using the method of Spearman-Kärber (Kärber G., Arch. Exp. Pathol. Pharmacol. 1931, 162: 480-483). The TCID<sub>50</sub>/carrier, i.e., the viral load per carrier, will be calculated as follows:

The Virus Load (TCID<sub>50</sub>/carrier) will be calculated in the following manner:

Virus Load (Log<sub>10</sub> TCID<sub>50</sub>) = Virus Titer (Log<sub>10</sub> TCID<sub>50</sub>/mL) + Log<sub>10</sub> [Volume per sample (mL)]

The Log<sub>10</sub> Reduction Factor (LRF) will be calculated in the following manner:

Log<sub>10</sub> Reduction Factor = Initial viral load (Log<sub>10</sub> TCID<sub>50</sub>, per assayed volume and per carrier) – Output viral load (Log<sub>10</sub> TCID<sub>50</sub>, per assayed volume and per carrier)

These analyses will be described in detail in the final report. The test results will be reported as the log<sub>10</sub> reduction of the virus titer per carrier and per volume post-treatment with the test substance.

#### **TEST ACCEPTANCE CRITERIA:**

The test will be acceptable for evaluation of the test results if the criteria listed below are satisfied. The study director may consider other causes that may affect test reliability and acceptance.

- The infectious virus recovered from the PRC control must be at least 4.8 log<sub>10</sub> TCID<sub>50</sub> units per carrier.
- Viral-induced cytopathic effect must be distinguishable from test substance induced cytotoxic effects (if any).
- Virus must be recovered from the neutralizer effectiveness/viral interference control (not exhibiting cytotoxicity).
- The Cell Viability Control (assay negative control) must not exhibit virus.

#### **TEST SUBSTANCE EVALUATION CRITERIA:**

According to the US Environmental Protection Agency, the test substance passes the test if the following are met:

- The product must demonstrate a  $\geq 3$  log<sub>10</sub> reduction on each surface in the presence or absence of cytotoxicity and taking into account the level of neutralization; and
- If cytotoxicity is present, the virus control titer should be increased, if necessary, to demonstrate a  $\geq 3$  log<sub>10</sub> reduction in viral titer on each surface beyond the cytotoxic and neutralization level.

## **PERSONNEL AND TESTING FACILITIES:**

A study director will be assigned prior to initiation of the test. Resumes are maintained and are available on request. This study will be conducted at Microbac Laboratories, Inc., 105 Carpenter Drive, Sterling, Virginia 20164.

## **REGULATORY COMPLIANCE AND QUALITY ASSURANCE (GLP studies only):**

This study will be performed in compliance with the US Environmental Protection Agency's Good Laboratory Practices (GLP) regulations, 40 CFR 160 (note: information on the identity, strength, purity, stability, uniformity, and dose solution analysis of the test substance/formula resides with the Sponsor of the study unless otherwise stated).

The Quality Assurance Unit of Microbac will inspect the conduct of the study for GLP compliance. The dates and a description of the phase(s) inspected, and the dates that findings are reported to management and the study director will be included in the final report.

## **PROTOCOL AMENDMENTS AND DEVIATIONS:**

Any protocol amendment(s) and protocol deviation(s) identified will be reported in project sheet(s) and included in the final report.

## **REPORT FORMAT:**

A draft report will be provided to the Sponsor for review prior to finalization. The report will contain all items required by EPA GLP (40 CFR Part 160.185), EPA 810.2000 (2018) and 810.2200 (2018) and be in compliance with EPA PR Notice 2011-3. Microbac employs a standard report format for each test design. Each final report will provide all the information in the citations above including (but not limited to):

- Sponsor identification
- Test substance identification
- Manufacture date for each product lot
- Type of assay and project number
- Study start and end time (clock time)
- Interpretation of results and conclusions

- Test results presented in tabular form
- Methods and evaluation criteria
- Description of protocol deviations and protocol amendments (if applicable)
- Dates of study initiation and completion (GLP studies only)
- Signed Quality Assurance and Compliance Statements (GLP studies only)
- Certificate of Analysis for each test lot (for GLP studies only; if provided by the Sponsor)
- List of personnel (and respective titles) involved in the study

#### **RECORDS TO BE MAINTAINED:**

For all GLP studies, the original signed final report or an electronic copy will be sent to the Sponsor. The original signed final report, or a copy thereof, will be maintained in the study file. If requested, a draft report will be provided to the Sponsor for review prior to finalization of the report.

All raw data, protocol, protocol modifications, test substance records, the final report (or copy thereof), and correspondence between Microbac and the Sponsor will be stored in the archives at Microbac Laboratories, Inc., 105 Carpenter Drive, Sterling, Virginia 20164 or in a controlled facility off site.

All changes or revisions to this approved protocol will be documented, signed by the study director, dated and maintained with this protocol. The Sponsor will be notified of any change, resolution, and impact on the study as soon as practical.

The proposed experimental start and termination dates, additional information about the test substance, challenge virus identity, host cell line monolayers, and the type of neutralizers employed in the test will be addressed in a project sheet issued separately for each study. The date the study director signs the protocol will be the study initiation date. All project sheets issued containing protocol amendments or deviations will be forwarded to the study Sponsor for approval and signature.

## REFERENCES (if applicable)

1. ASTM E1053-20, Standard Test Method to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces, ASTM International, West Conshohocken, PA, 2020.
2. U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2200: Disinfectants for Use on Environmental Surfaces, Guidance for Efficacy Testing, February 2018.
3. U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2000: General Considerations for Testing Public Health Antimicrobial Pesticides, Guidance for Efficacy Testing, February 2018.
4. U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, Frequently Asked Questions (FAQ) for OCSPP 810.2000, 810.2100, and 810.2200, August 2019.
5. Health Canada, January 2014. Guidance Document – Disinfectant Drugs.
6. Health Canada, January 2014. Guidance Document – Safety and Efficacy Requirements for Hard Surface Disinfectant Drugs.
7. U.S. Environmental Protection Agency, Office of Pesticide Programs Microbiology Laboratory SOP MB-30-02: Standard Operating Procedure for Preparation of Hard Water and Other Diluents for Preparation of Antimicrobial Products, August 21, 2019.
8. Association of Official Analytical Chemists (AOAC) International, Official Method 960.09: Germicidal and Detergent Sanitizing Action of Disinfectants. Official Methods of Analysis of the AOAC, 2013 edition.
9. Organisation for Economic Co-operation and Development (OECD) Guidance Document on Quantitative Methods for Evaluating the Activity of Microbicides Used on Hard Non-Porous Surfaces. Series on Testing Assessment No. 187 and Series on Biocides No. 6, June 21, 2013.

**MISCELLANEOUS INFORMATION:**

The following information is to be completed by the Sponsor prior to initiation of the study (please check all applicable open boxes):

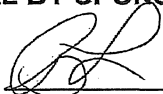
**B. Test substance information:**

Test substance name	Condor 2		
EPA Reg. No.	NA	NA	NA
Test substance lot numbers	KK007-64	KK007-65	KK007-66
Manufacture Date	03/26/2020	03/26/2020	03/26/2020
Expiration Date	NA	NA	NA
Active ingredient(s)	0.48% Quaternary ammonium compounds		
Test substance storage conditions	<input checked="" type="checkbox"/> Ambient <input type="checkbox"/> Refrigerated <input type="checkbox"/> Other: _____		
Level of active ingredients in testing	<input checked="" type="checkbox"/> Lower Certified Limit (LCL) <input type="checkbox"/> At or below nominal		
SDS provided	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	C of A provided	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Dilution	<input checked="" type="checkbox"/> Ready to use <input type="checkbox"/> _____ (_____ parts test substance + _____ parts diluent)		
Diluent	<input checked="" type="checkbox"/> Not applicable <input type="checkbox"/> 400 ppm $\pm$ 2.9% AOAC hard water <input type="checkbox"/> 375 ppm OECD hard water (acceptable range: 338-394 ppm) <input type="checkbox"/> 200 ppm unsoftened tap water (acceptable range: 180-210 ppm) <input type="checkbox"/> Other: _____		
Contact time	1 minute		
Contact temperature	<input checked="" type="checkbox"/> Room Temperature (20 $\pm$ 1°C) <input type="checkbox"/> Other : _____		
Organic Load	<input type="checkbox"/> 5.0% serum in viral inoculum <input checked="" type="checkbox"/> Other: <u>5.0% Fetal Bovine Serum in viral inoculum</u>		

Test substance information (continued):


Test substance preparation (spray)	<input type="checkbox"/> Shake sprayer _____ times and spray into waste container to prime before use <input checked="" type="checkbox"/> Do not shake sprayer; spray into waste container to prime before use <input type="checkbox"/> Other: _____ <input type="checkbox"/> Not applicable
Test substance application	<input type="checkbox"/> Apply directly to dried virus via pipetting <input checked="" type="checkbox"/> Spray from <u>6-8</u> inches using <u>3</u> sprays or until thoroughly wet <input type="checkbox"/> Spray from _____ inches for _____ seconds or until thoroughly wet <input type="checkbox"/> Other: _____
Study conduct	<input checked="" type="checkbox"/> GLP <span style="margin-left: 100px;"><input type="checkbox"/> Non-GLP</span>
Report submission	<input checked="" type="checkbox"/> EPA <span style="margin-left: 50px;"><input checked="" type="checkbox"/> Health Canada</span> <span style="margin-left: 50px;"><input type="checkbox"/> Other: _____</span>

**PROTOCOL APPROVAL BY SPONSOR:**

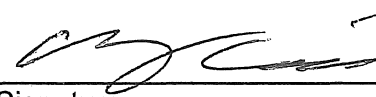
Sponsor Signature:  Date: 05/08/2020


Printed Name: Becky Lien


**PROTOCOL APPROVAL BY STUDY DIRECTOR (Microbac):**

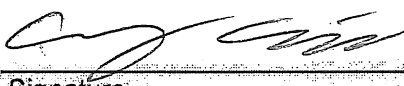

Study Director Signature:  Date: 05/28/20

Printed Name: Cory Chiossone

Date Issued: 05/28/20		Project Sheet No. 1		Page No. 1		Laboratory Project Identification No. 640-105	
<b>STUDY TITLE:</b> VIRUCIDAL HARD-SURFACE EFFICACY TEST – Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-CoV-2) (COVID-19 Virus)				<b>STUDY DIRECTOR:</b> Cory Chiossone			
				 Signature		05/28/20 Date	
<b>TEST MATERIAL(S):</b> Condor 2				<b>LOT NO.</b> KK007-64 KK007-65 KK007-66		<b>DATE RECEIVED:</b> 04/01/20 04/01/20 04/01/20	
<b>PERFORMING DEPARTMENT(S):</b> Virology and Toxicology				<b>DS NO.</b> K340 K341 K342			
				<b>STORAGE CONDITIONS:</b> Location: F6 <input type="checkbox"/> Dark <input checked="" type="checkbox"/> Ambient Room Temperature <input type="checkbox"/> Desiccator <input type="checkbox"/> Freezer <input type="checkbox"/> Refrigerator <input type="checkbox"/> Other:			
<b>PROTECTIVE PRECAUTION REQUIRED:</b> MSDS <input checked="" type="checkbox"/> Yes / <input type="checkbox"/> No							
<b>PHYSICAL DESCRIPTION:</b> <input type="checkbox"/> Solid <input checked="" type="checkbox"/> Liquid <input type="checkbox"/> Aerosol							
<b>PURPOSE:</b> See attached protocol. <b>AUTHORIZATION:</b> See client signature.							
<b>PROPOSED EXPERIMENTAL START DATE:</b> 05/28/20 <b>TERMINATION DATE:</b> 06/06/20							
<b>CONDUCT OF STUDY:</b> <input type="checkbox"/> FDA <input checked="" type="checkbox"/> EPA <input type="checkbox"/> R&D <input checked="" type="checkbox"/> GLP <input type="checkbox"/> GCP <input checked="" type="checkbox"/> Other: Health Canada							
<b>SPONSOR:</b> W.M. Barr & Company, Inc. 6750 Lenox Center Court Suite 200 Memphis, TN 38115				<b>CONTACT PERSON:</b> Becky Lien blien@srcconsultants.com			
<b>TEST CONDITIONS:</b>							
<b>Challenge organisms:</b>		Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (COVID-19 Virus), Strain USA-WA1/2020; BEI Resources, NR-52281					
<b>Host:</b>		Vero E6 cells, ATCC CRL-1586					
<b>Organic load:</b>		5.0% serum in viral inoculum					
<b>Disinfectant application:</b>		Spray from 6-8 inches until thoroughly wet.					
<b>Active Ingredient:</b>		0.48% Quaternary ammonium compounds					
<b>Dilution medium:</b>		Minimum Essential Medium (MEM) + 2% Newborn Calf Serum (NCS)					
<b>Dilution:</b>		Ready to use					
<b>Diluent:</b>		N/A					
<b>Neutralizer(s):</b>		MEM + 10% NCS + 0.5% Lecithin + 0.5% Polysorbate-80 + 1% HEPES					
<b>Contact time:</b>		1 minute					
<b>Contact temperature:</b>		Ambient room temperature (20±1°C)					
<b>Incubation time(s):</b>		4 – 9 days					
<b>Incubation temperature(s):</b>		36±2C in 5±3% CO <sub>2</sub>					

Date Issued: 06/26/20		Project Sheet No. 2		Page No. 1		Laboratory Project Identification No. 640-105	
<b>STUDY TITLE:</b> VIRUCIDAL HARD-SURFACE EFFICACY TEST – Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-CoV-2) (COVID-19 Virus)				<b>STUDY DIRECTOR:</b> Cory Chiossone			
				 Signature		06/26/20 Date	
<b>TEST MATERIAL(S):</b> Condor 2				<b>LOT NO.</b> KK007-64 KK007-65 KK007-66	<b>DATE RECEIVED:</b> 04/01/20 04/01/20 04/01/20	<b>DS NO.</b> K340 K341 K342	
<b>PERFORMING DEPARTMENT(S):</b> Virology and Toxicology				<b>STORAGE CONDITIONS:</b> Location: F6 <input type="checkbox"/> Dark <input checked="" type="checkbox"/> Ambient Room Temperature <input type="checkbox"/> Desiccator <input type="checkbox"/> Freezer <input type="checkbox"/> Refrigerator <input type="checkbox"/> Other:			
<b>PROTECTIVE PRECAUTION REQUIRED:</b> MSDS <input checked="" type="checkbox"/> Yes / <input type="checkbox"/> No							
<b>PHYSICAL DESCRIPTION:</b> <input type="checkbox"/> Solid <input checked="" type="checkbox"/> Liquid <input type="checkbox"/> Aerosol							
<b>PURPOSE:</b> See attached protocol. <b>AUTHORIZATION:</b> See client signature.							
<b>PROPOSED EXPERIMENTAL START DATE:</b> 05/28/20 <b>TERMINATION DATE:</b> 06/06/20							
<b>CONDUCT OF STUDY:</b> <input type="checkbox"/> FDA <input checked="" type="checkbox"/> EPA <input type="checkbox"/> R&D <input checked="" type="checkbox"/> GLP <input type="checkbox"/> GCP <input checked="" type="checkbox"/> Other: Health Canada							
<b>SPONSOR:</b> W.M. Barr & Company, Inc. 6750 Lenox Center Court Suite 200 Memphis, TN 38115				<b>CONTACT PERSON:</b> Becky Lien blien@srcconsultants.com			
<b>PROTOCOL AMENDMENT(S):</b>  1. Project Sheet No. 1: The challenge organism is listed as "Severe Acute Respiratory Syndrome Coronavirus 2". It should be "Severe Acute Respiratory Syndrome-related Coronavirus 2 (SARS-CoV-2) (COVID-19 Virus) (SARS-Related Coronavirus 2)". This amendment serves to correct the typographical error on Project Sheet No. 1.							

Date Issued: 07/15/20    Project Sheet No. 3    Page No. 1    Laboratory Project Identification No. 640-105													
<b>STUDY TITLE:</b> VIRUCIDAL HARD-SURFACE EFFICACY TEST – Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-CoV-2) (COVID-19 Virus)	<b>STUDY DIRECTOR:</b> Cory Chiossone  <div style="display: flex; justify-content: space-between;"> <span>Signature</span> <span>07/16/20 Date</span> </div>												
<b>TEST MATERIAL(S):</b> Condor 2	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: left;">LOT NO.</th> <th style="text-align: left;">DATE RECEIVED:</th> <th style="text-align: left;">DS NO.</th> </tr> <tr> <td>KK007-64</td> <td>04/01/20</td> <td>K340</td> </tr> <tr> <td>KK007-65</td> <td>04/01/20</td> <td>K341</td> </tr> <tr> <td>KK007-66</td> <td>04/01/20</td> <td>K342</td> </tr> </table>	LOT NO.	DATE RECEIVED:	DS NO.	KK007-64	04/01/20	K340	KK007-65	04/01/20	K341	KK007-66	04/01/20	K342
LOT NO.	DATE RECEIVED:	DS NO.											
KK007-64	04/01/20	K340											
KK007-65	04/01/20	K341											
KK007-66	04/01/20	K342											
<b>PERFORMING DEPARTMENT(S):</b> Virology and Toxicology	<b>STORAGE CONDITIONS:</b> Location: F6 <input type="checkbox"/> Dark <input checked="" type="checkbox"/> Ambient Room Temperature <input type="checkbox"/> Desiccator <input type="checkbox"/> Freezer <input type="checkbox"/> Refrigerator <input type="checkbox"/> Other:												
<b>CONDUCT OF STUDY:</b> <input type="checkbox"/> FDA <input checked="" type="checkbox"/> EPA <input type="checkbox"/> R&D <input checked="" type="checkbox"/> GLP <input type="checkbox"/> GCP <input checked="" type="checkbox"/> Other: Health Canada													
<b>SPONSOR:</b> W.M. Barr & Company, Inc. 6750 Lenox Center Court Suite 200 Memphis, TN 38115	<b>CONTACT PERSON:</b> Becky Lien blien@srcconsultants.com												
<b>PROTOCOL AMENDMENT(S):</b>  2. Project Sheet No. 1: The project sheet should mention that the carriers were to be sprayed from 6-8 inches using three sprays until thoroughly wet. This amendment serves to include the test substance application instructions to Project Sheet No. 1.													

Date Issued: 07/21/20		Project Sheet No. 4		Page No. 1		Laboratory Project Identification No. 640-105	
<b>STUDY TITLE:</b> VIRUCIDAL HARD-SURFACE <b>EFFICACY TEST</b> = Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-CoV-2) (COVID-19 Virus)				<b>STUDY DIRECTOR:</b> Cory Chiossone  07/21/20 Signature Date			
<b>TEST MATERIAL(S):</b> Condor 2				<b>LOT NO.</b> KK007-64 KK007-65 KK007-66		<b>DATE RECEIVED:</b> 04/01/20 04/01/20 04/01/20	
<b>TESTING DEPARTMENT(S):</b> Virology and Toxicology				<b>STORAGE CONDITIONS:</b> Location: F6 <input type="checkbox"/> Dark <input checked="" type="checkbox"/> Ambient Room Temperature <input type="checkbox"/> Desiccator <input type="checkbox"/> Freezer <input type="checkbox"/> Refrigerator <input type="checkbox"/> Other:			
<b>CONDUCT OF STUDY:</b> <input type="checkbox"/> FDA <input checked="" type="checkbox"/> EPA <input type="checkbox"/> R&D <input checked="" type="checkbox"/> GLP <input type="checkbox"/> GCP <input checked="" type="checkbox"/> Other: Health Canada							
<b>SPONSOR:</b> W.M. Barr & Company, Inc. 6750 Lenox Center Court Suite 200 Memphis, TN 38115				<b>CONTACT PERSON:</b> Becky Lien blien@srcconsultants.com			
<b>PROTOCOL AMENDMENTS:</b>							
3. The records to be maintained section of the protocol states that all protocol amendments and deviations will be sent to Sponsor for approval and signature. It should state that "all protocol amendments and deviations related to test procedure will be sent to Sponsor for approval and signature". This amendment serves to clarify the protocol regarding this statement							
4. The References section of the Protocol give References 5 and 6 as:							
5. Health Canada, January 2014. Guidance Document – Disinfectant Drugs.							
6. Health Canada, January 2014. Guidance Document – Safety and Efficacy Requirements for Hard Surface Disinfectant Drugs.							
These references should be:							
5. Health Canada, April 2020. Guidance Document – Disinfectant Drugs.							
6. Health Canada, April 2020. Guidance Document – Safety and Efficacy Requirements for Surface Disinfectant Drugs.							
This amendment serves to update references 5 and 6 in the References section of the Protocol.							
Amendment(s) to or deviation(s) from the protocol accepted by the sponsor:							
 Signature				7/21/2020 Date			